

# SoftComply

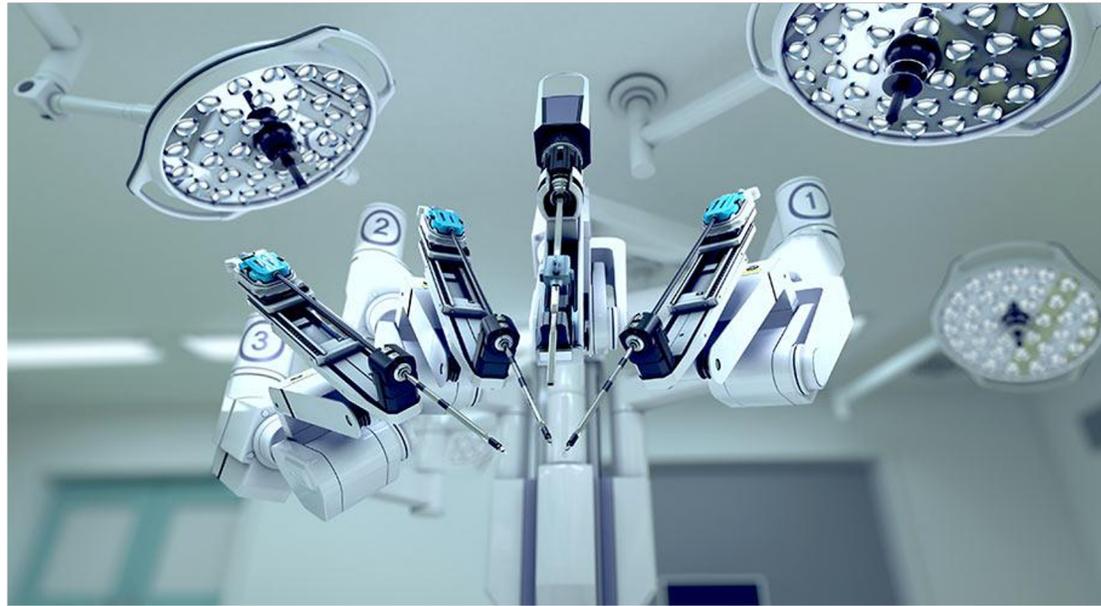
- compliance made easy -



# REGULATED INDUSTRIES



## THREAT TO HUMAN LIVES



50'000 MEDTECH CO-s  
90% SMEs  
\$60bn spent on Compliance a year



# REGULATIONS & AGILE

## REGULATORY COMPLIANCE

- FDA 21 CFR Part 820
- Medical Device Regulations
- ISO 13485
- ISO 14971
- IEC 62304



**SOFTCOMPLY TOOLS  
HELP AUTOMATE  
REGULATORY  
COMPLIANCE**

## SOFTWARE TRENDS

- Increasing amount of software in medical devices
- Increasingly open enterprise software platforms



**MORE SOFTWARE**



**OPEN PLATFORMS**

# AIM: CUTTING REGULATORY COSTS 10X

## OUR MAIN CONSIDERATION:



INTEGRATION

- Building regulatory compliance into software development lifecycle



COST

- Integrated to Atlassian tools Jira and Confluence



TIME

- Low entry price for SMEs
- Cutting regulatory cost 10x
- Faster time to market



# AUTOMATING COMPLIANCE

## DOCUMENT MANAGEMENT APPS



DOCUMENT MANAGEMENT APP WITH COMPLIANT WORKFLOWS & E-SIGNATURES



AUTOMATED VALIDATION APP FOR CONFLUENCE CLOUD



AUTOMATED VALIDATION APP FOR THE RISK MANAGER PLUS



FREEZING THE DYNAMIC CONTENT ON CONFLUENCE PAGES

## RISK MANAGEMENT APPS



THE INFORMATION SECURITY RISK MANAGEMENT APP FOR ISO/IEC 27001 COMPLIANCE



THE MOST ADVANCED RISK MANAGEMENT APP ON JIRA CLOUD



RISK REPORTING ON CONFLUENCE CLOUD FOR OUR RISK APPS on JIRA



THE RISK MANAGEMENT APP FOR SIMPLE PROJECT RISKS

OVER 1000 CLIENTS

**AIRBUS**



**ThermoFisher**  
SCIENTIFIC



**BOEING**



Dentsply  
Sirona



**LILIUM**

**MCKESSON**

# COMPLIANCE MADE EASY

Automating Regulatory Compliance on Atlassian Jira & Confluence

 Jira



**The Most Powerful Risk Management Solution**



**The only Information Security Risk Management Solution for ISO 27001 compliance**

 Confluence



**Automated Integrity Checks of your Confluence Cloud**



**The Document Management solution on Confluence Cloud**



**Report Risks in Confluence Cloud**



**Freeze the Dynamic Content on Confluence Pages**



**Compliant medical device Quality System Documentation**

# SOFTCOMPLY DOCUMENT MANAGER

Dashboard Containers Folders Manage

Home Recent Spaces Teams Apps Templates Invite people Create Search

## SoftComply Document Manager (Development)

SoftComply Compliance made easy

Home dashboard

### My Containers

Name	Type	Workflow step	Status
MyContainer	General		Draft
Test Release Template	General		Released
Test Template release	General		Released

Dashboard Containers Folders Manage

**Review and approve** ACTIVE

This workflow is used to review and approve documents

Created on:  
2023-06-06 11:21:00

Container Templates  
Fields  
Workflows

```
graph TD; InReview[In Review] -- "Send to Approval" --> InApproval[In Approval]; InApproval -- "Approve" --> Approved[Approved];
```

Compliant **Document Management Solution** on Confluence Cloud

# SOFTCOMPLY INFORMATION SECURITY MANAGER

The screenshot displays the Jira interface for the 'ISO/IEC 27001 Asset-Based Risk Management for Project Information Security Risk Project'. The left panel shows a table of risks with columns for Risk/Threat Progress, Assets from Assets Register, Risk ID, Risk/Threat, Cause of Threat / Vulnerability, and Initial Threat Consequence. The right panel shows the 'ISO/IEC 27001 Checklist' with a progress bar at 50.00%. The checklist table has columns for Progress, ISO/IEC 27001 Requirement, Type of Evidence, Requirement Description, Completed, and Source. The requirements listed are Clause 4: Context of the organization and Clause 5: Leadership, InfoSec Policy and Roles & Responsibilities.

Progress	ISO/IEC 27001 Requirement	Type of Evidence	Requirement Description	Completed	Source
50.00%	<b>Clause 4: Context of the organization</b> <i>The organisation shall determine the context, the scope and the needs of the interested parties relevant to the information security management system.</i>		List all the internal and external issues that are relevant and affect organization's Information Security Management System [4.1].	<input checked="" type="checkbox"/>	Link Web page
			List all the relevant parties and their Information Security requirements [4.2].	<input type="checkbox"/>	URL https://example.com
			Define the scope of the Information Security Management System [4.3]: <ul style="list-style-type: none"><li>does it apply to the entire organization?</li><li>which internal processes are related to the ISMS?</li><li>which external processes are addressed in the ISMS?</li></ul>	<input type="checkbox"/>	Link text Add a description... Cancel Add
			Information Security Management System continuous improvement processes established [4.4] e.g. yearly management reviews etc.	<input checked="" type="checkbox"/>	Link Confluence page Search page(s) Cancel Add
25.00%	<b>Clause 5: Leadership, InfoSec Policy and Roles &amp; Responsibilities</b> <i>Organisation's top management shall demonstrate commitment to the information security management system; they shall establish an information security policy and they shall ensure that responsibilities and authorities for infosec roles are assigned and</i>		Is your leadership committed to establishing and continuously improving the Information Security Management System? <ul style="list-style-type: none"><li>necessary support and resources are provided to implement and maintain the Information Security Management System?</li></ul>	<input type="checkbox"/>	Link Confluence page Search page(s) Cancel Add

The only **Information Security Risk Management Solution** on Jira Cloud supporting compliance with ISO/IEC 27001

# SOFTCOMPLY RISK MANAGER PLUS

The screenshot displays the 'Risk Management for Project Product Risks' interface within Jira Cloud. It features a 'Risk Matrix' and an 'FMEA Scale'.

**Risk Matrix:** A table showing the relationship between Initial Risk (rows) and Residual Risk (columns) based on various factors. The matrix is color-coded by risk level: Green for Low, Yellow for Medium, and Red for High.

INITIAL	1 Negligible	2 Minor	3 Serious	4 Critical	5 Catastrophic
LOW	MEDLM	MEDLM	HIGH	HIGH	HIGH
MEDIUM	LOW	MEDLM	HIGH	HIGH	HIGH
HIGH	LOW	LOW	MEDLM	HIGH	HIGH

**FMEA Scale:** A table defining the FMEA Scale with Occurrence, Severity, and Detectability values.

Occurrence	Severity	Detectability	Title	Description
1	5	1	Frequent	Occurring often or repeatedly
2	4	2	Probable	Reasonably likely to occur
3	3	3	Occasional	Irregular occurrence, infrequent
4	2	4	Remote	Not likely to occur
5	1	5	Improbable	Unlikely to ever occur

Below the FMEA Scale is a summary table showing the range of risk counts and their corresponding levels and colors.

Range	Level	Color	Initial risk count	Residual risk count
65 - 125	D	Red	1	0
33 - 64	C	Yellow	2	0
19 - 32	B	Green	0	1
1 - 18	A	Green	0	2

The Most Advanced **Risk Management Solution** on Jira Cloud **for any Risk Management Method**

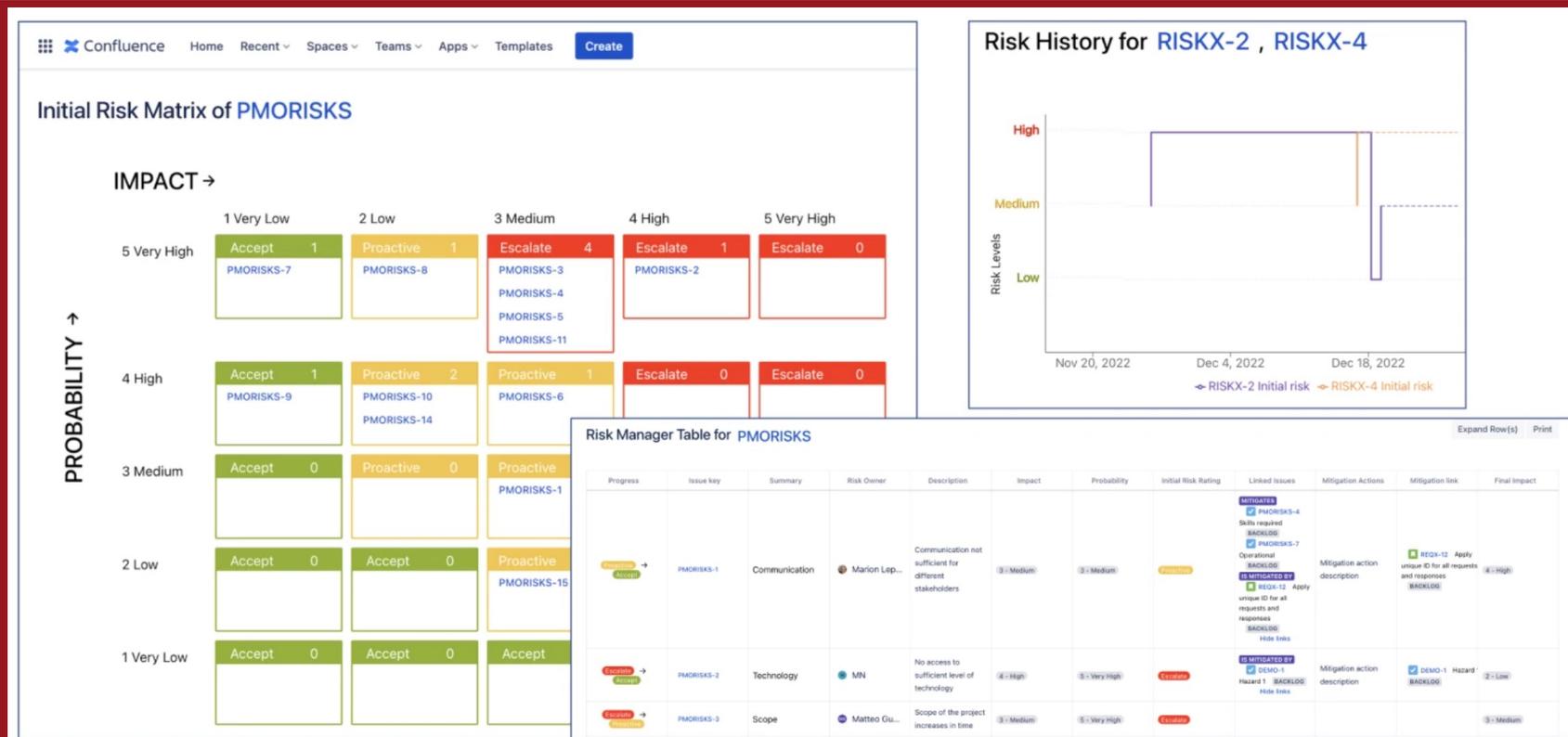
# SOFTCOMPLY RISK MANAGER

The image displays two views of the Jira Risk Manager interface. The left view shows a 'Risk Matrix My Product Risks' with a grid of risk levels (Negligible, Minor, Serious, Critical, Catastrophic) and frequencies (Frequent, Probable, Occasional, Remote, Improbable). The right view shows a detailed 'Risk Management for Project My Product Risks' table with columns for Risk, Hazard, Hazardous Situation, Harm, Cause, Severity, Probability, Risk, Mitigation Action, Mitigation Links, and Verification.

RISK	HAZARD	HAZARDOUS SITUATION	HARM	CAUSE	SEVERITY	PROBABILITY	RISK	MITIGATION ACTION	MITIGATION LINKS	VERIFICATION
Medium	MPR-10: Biological	Cross contamination of patients	Infection	Blood not cleaned adequately off the device	3	2	Medium	Design device for cleanability	DEV-3 Design device for cleanability TO DO	ref. V&V report, test #122
Medium	Biological	Cross contam	Infection	Device not s	3	2	Medium	Design dev	DEV-3 x	ref. V&V report, test #121
Medium	MPR-19: Biological	Cross contamination of patients	Infection	Sharp edges cut through sterile barrier	3	2	Medium	Round any sharp edges	DEV-4 Round any sharp edge DO	V&V report, test #121
Medium	MPR-11: Biological	Cross infection of user	Infection	Sharp edges cut through sterile barrier	3	2	Medium	Round any sharp edge	DEV-4 Round any sharp edge DONE	Ref. V&V report, test #121

Fully customizable **Product Risk Management Solution** on Jira (Cloud & Server/DC) for software system safety or security risk management

# SOFTCOMPLY RISK REPORTING



The **Risk Reporting extension on Confluence Cloud** for SoftComply Risk Manager & Risk Manager Plus

# VALIDATION FOR CONFLUENCE

Run Tests Manually ? Execute Tests

Status and Details of your Validation Tests Validation App page

Enable automatic test execution: ?

Select a weekday: Monday

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday
- Saturday
- Sunday

Confluence Home Recent Spaces People Apps Templates Create

## Validation report Tue Jan 10 13:18:46 UTC 2023

Created by SoftComply Yesterday at 1:26 pm • 56 min read • 1 person viewed • Add Workflow • Unlocked • Version Notes

- Validation Report
  - Validation Results
    - TC-CON-001 Log into user administration with user1 and make sure all necessary first time dialogs are dismissed ✓
    - TC-CON-002 Log in with user1 and make sure all necessary first time dialogs are dismissed ✓
    - TC-CON-003 Make sure user2 cannot access site ✓
    - TC-CON-004 User2 should not be able to access site ✓
    - TC-CON-005 Grant confluence access to user2 ✓
    - TC-CON-006 Log in with user2 and make sure all necessary first time dialogs are dismissed ✓
    - TC-CON-007 Verify space does not exist ✓
    - TC-CON-008 User with configured credentials can access Confluence ✓
    - TC-CON-009 Import space from zip file ✓
    - TC-CON-010 Create new space for validation ✓
    - TC-CON-011 Create a page with multiple edits and restore its previous state ✓
    - TC-CON-012 Create page with restricted access ✓
    - TC-CON-013 Create a page for moving in temporary test space ✓

Run **Regular Integrity Checks** of your **Confluence Cloud instance** with the SoftComply Validation app for Confluence

# VALIDATION FOR RISK MANAGER PLUS

The screenshot displays the Risk Manager Plus validation interface. On the left, there are controls for running tests manually, a status section, a toggle for automatic test execution (which is turned on), and a dropdown menu for selecting a weekday (currently set to Monday). On the right, a validation report is shown for Wednesday, August 30, 2023, at 08:37:42 UTC. The report lists 21 test cases, all of which have passed, indicated by green checkmarks.

Run Tests Manually ? Execute Tests

Status and Details of your Validation Tests Validation App page

Enable automatic test execution: ?

Select a weekday: Monday

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday
- Saturday
- Sunday

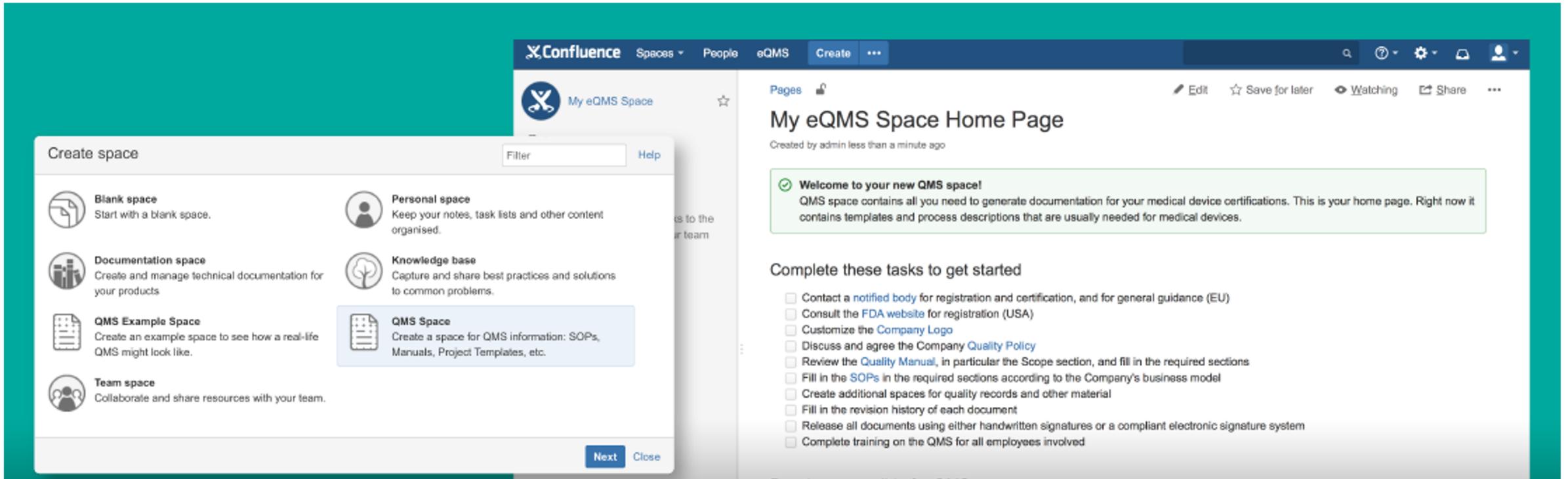
Validation report Wed Aug 30 08:37:42 UTC 2023

Owned by SoftComply ...  
Yesterday at 12:19 pm · 9 min read · 1 person viewed

- Validation Report
  - Tests summary
  - Validation Results
    - TC-RMP-002 - Check if admin can see Risk Model ✓
    - TC-RMP-003 - Check if admin can see Risk Table ✓
    - TC-RMP-004 - Check if standard user has access to Risk Manager Plus ✓
    - TC-RMP-005 - Check if standard user has access to Risk Manager Plus from project ✓
    - TC-RMP-006 - Check creation of the RPN by admin ✓
    - TC-RMP-007 - Check creation of the RPN with editing Risk Iteration ✓
    - TC-RMP-008 - Check creation of the RPN with adding Risk Iteration ✓
    - TC-RMP-009 - Check creation of the RPN with deleting Risk Iteration ✓
    - TC-RMP-010 - Check creation of the RPN with adding new Characteristic ✓
    - TC-RMP-011 - Check creation of the RPN with adding new level to the existing Characteristic ✓
    - TC-RMP-012 - Check creation of the RPN with editing level of the existing Characteristic ✓
    - TC-RMP-013 - Create RPN Risk model and remove one of the levels ✓
    - TC-RMP-014 - Create RPN and change values of risk level on the step 'Define Risk Classes/Levels' ✓
    - TC-RMP-015 - Create RPN and delete risk level on the step 'Define Risk Classes/Levels' ✓
    - TC-RMP-016 - Check creation of the 2 dimensional matrix based risk model by admin ✓
    - TC-RMP-017 - Creation of 3 dimensional matrix based risk model by admin ✓
    - TC-RMP-018 - Check linking of Risk Model with 2 dim to the project from the Risk Management Plus Global page ✓
    - TC-RMP-019 - Check linking of Risk Model with 3 dim to the project from the Risk Management Plus Global page ✓
    - TC-RMP-020 - Check linking of Risk Model with 2 dim to the project from the project page ✓
    - TC-RMP-021 - Check linking of Risk Model with 3 dim to the project from the project page ✓

Run **Regular Integrity Checks** of your **Risk Manager Plus** on your **Jira Cloud** instance

# SOFTCOMPLY eQMS

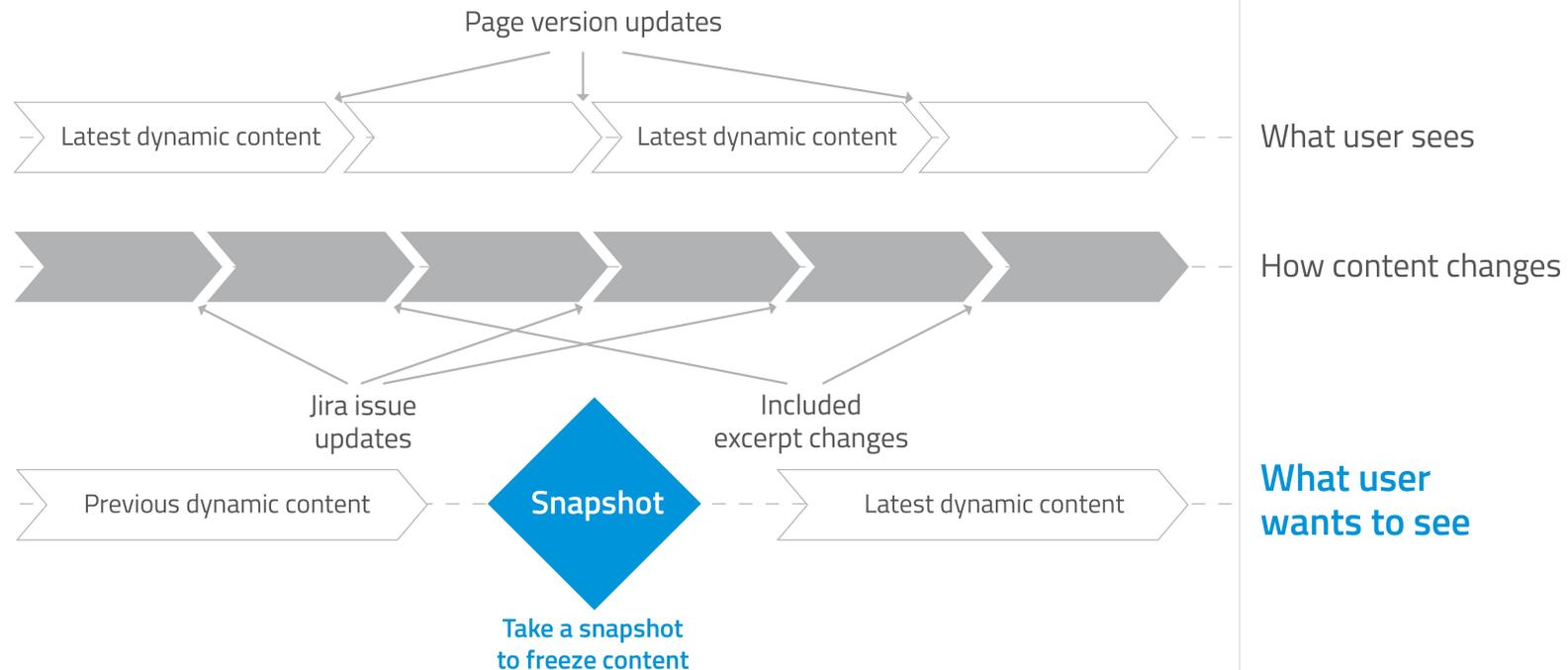


Full **medical device Quality System on Confluence** with embedded instructions and guidance to customization, **fully compliant with EU and US regulations**

# SOFTCOMPLY STATIC SNAPSHOTS



Page in Confluence



The SoftComply Static Snapshots to Freeze the **Dynamic Content** on **Confluence Pages**

# CHANGE HISTORY

The screenshot shows a Confluence page titled "SoftComply Change History Table for Confluence Cloud". At the top right, there is a blue button labeled "Add Version Notes". Below it, a modal window is open with the title "Version Note for Version 3 in SoftComply Change History Table". The modal contains a text input field with the word "None" and a "Submit" button. Below the modal, a table displays the document's change history.

Version	Effective Date	Approvals	Version Notes
1	Tue, 17 May 2022 08:29:05 GMT	→ Publisher - Approval; Action: approve (Tue, 17 May 2022 08:20:38 GMT) → Matteo Gubellini - Approval; Action: approve (Tue, 17 May 2022 08:17:17 GMT)	Initial Release
2	Tue, 17 May 2022 08:37:05 GMT	→ Publisher - Approval; Action: approve (Tue, 17 May 2022 08:34:52 GMT) → Matteo Gubellini - Approval; Action: approve (Tue, 17 May 2022 08:32:52 GMT)	Section 3.1 updated to reflect the latest FDA guidance on software development.
3 (Draft)			None

Add **Approval History** to your **Confluence Page** with the SoftComply Change History app

# HOW TO REACH US



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 [@SoftComply](https://twitter.com/SoftComply)

 [/company/softcomply/](https://www.linkedin.com/company/softcomply/)



 [facebook.com/softcomply](https://facebook.com/softcomply)

 [SoftComply channel](#)